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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,764	07/27/2001	Tiziana Bisogno	2865-332	7567

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,764	BISOGNO ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-26 and 51-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed March 31, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-21 and 27-50 have been canceled.

2. Claims 22 and 52 have been amended.

4. Remarks drawn to rejections under 35 USC 102

Claims 22-26 and 51-53 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-26 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast tumor and prostate carcinoma, does not reasonably provide enablement for the treatment of peripheral, somatic or autonomic neuropathies, multiple sclerosis, hypertrophic or cheloid cicatrisation, psoriasis, urticaria, urticaria-angioedema syndrome, a pathology mediated by hyperreactivity of the vaginal or vulvo-vaginal canal, arthritis and a pathology mediated by hyperactivity of the bladder mucosa. The specification does not enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The state of the prior art
© The level of one of ordinary skill
(D) The level of predictability in the art
(E) The amount of direction provided by the inventor
(F) The existence of working examples
(G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 22-26 and 51-53 are drawn to for the treatment of breast tumor and prostate carcinoma, does not reasonably provide enablement for the treatment of peripheral, somatic or autonomic neuropathies, multiple sclerosis, hypertrophic or cheloid cicatrisation, psoriasis, urticaria, urticaria-angioedema syndrome, a pathology mediated by hyperreactivity of the vaginal or vulvo-vaginal canal, arthritis and a pathology mediated by hyperactivity of the bladder mucosa. The breadth of the claims is seen to include several disorders and conditions.

The state of the prior art

The examiner notes that the art cited by the applicants and the prior art of record, are drawn to vanilloids that are nociceptors (Dray and Winter et al, IDS), which also

inhibit melanoma and cancer/tumor cell (More et al) lines. However, there is no teaching of the treatment of other diseases and conditions in the prior art. One of ordinary skill in the art would not extrapolate the information in the prior at to the treatment of all of the said diseases and conditions.

The level of predictability in the art

The examiner acknowledges the probability and predictability that the instantly claimed compounds may have a reasonable expectation of success. There is not seen sufficient data to substantiate the treatment of the said diseases and conditions.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the treatment of peripheral, somatic or autonomic neuropathies, multiple sclerosis, hypertrophic or cheloid cicatrisation, psoriasis, urticaria, urticaria-angioedema syndrome, a pathology mediated by hyperreactivity of the vaginal or vulvo-vaginal canal, arthritis and a pathology mediated by hyperactivity of the bladder mucosa. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for the said treatment.

The existence of working examples

The working examples set forth in the instant specification are drawn to the effect of the said compounds on breast and prostate cell lines and the effect of the binding of the compounds on the binding of the CB1 receptors. Despite these examples there is little enabling disclosure for the treatment of peripheral, somatic or autonomic neuropathies,

multiple sclerosis, hypertrophic or cheloid cicatrisation, psoriasis, urticaria, urticaria-angioedema syndrome, a pathology mediated by hyperreactivity of the vaginal or vulvo-vaginal canal, arthritis and a pathology mediated by hyperactivity of the bladder mucosa. Applicant has given working examples of the effect of the compounds on tumor and cancer cell lines only. Based on this one of ordinary skill in the art cannot predict or extrapolate it to the treatment of all the diseases and conditions as instantly claimed.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the use of the instant compounds for the treatment of peripheral, somatic or autonomic neuropathies, multiple sclerosis, hypertrophic or cheloid cicatrisation, psoriasis, urticaria, urticaria-angioedema syndrome, a pathology mediated by hyperreactivity of the vaginal or vulvo-vaginal canal, arthritis and a pathology mediated by hyperactivity of the bladder mucosa. One of ordinary skill in the art would have to carry out experimentation in order to determine the efficacy of the said compounds in the said methods of treatment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22-26 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites functionally stimulating treating. It is not clear what stimulating treating means. The recitation is interpreted to mean either or both.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Response to Remarks/Arguments

Applicants have amended claims 22 and 52 to exclude asthma, melanoma, anti-inflammatory and antinociceptive activity and argue that the claims as amended are not anticipated by the prior art.

This is not found to be persuasive. Morre et al teach the use of capsaicin for the inhibition of tumor cell lines by capsaicin-induced apoptosis. This teaching of Morrre et al still reads on the instant claims. The rejection of claims 22 and 52 is being maintained.

Conclusion

Claims 22-26 and 51-53 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK